Docket No.: COTH-P01-001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Afeyan *et al.*	Confirmation No.: 7920
Application No.: 10/650592	Art Unit: 1652
Filed: August 27, 2003	
For: ADZYMES AND USES THEREOF	Examiner: MEAH, M.Y.

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This response is filed in reply to the outstanding Restriction Requirement, mailed August 11, 2005, in connection with the above application. The period for response has been extended to January 11, 2006, by the accompanying petition for FOUR-month extension. Applicants hereby elect Group I (Claims 1-134), with traverse, on the following grounds.

Applicants submit that claims in all groups are closely related, such that a search of the Group I claims would necessarily entail searching the subject matter of the remaining Groups. Applicants' position is further supported by the fact that Groups II – IV contain claims dependent on Group I claims. Therefore, reconsideration and withdrawal of the restriction requirement among the Groups, at least among Groups I – IV, are respectfully requested.

The Office Action also requires Applicants to elect a specific adzyme fusion protein if any one of Groups I – VI is elected. Specifically, the Restriction Requirement requires Applicants to elect a <u>specific combination</u> of adzyme fusion protein, by selecting one specific protease or proteinase domain and one specific targeting domain. For the reasons below, Applicants believe that the Restriction Requirement would be improper if the Restriction is not

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interpreted as requiring Applicants to elect a species adzyme for *search purpose* only. Applicants hereby elect *with traverse*, and *for search purpose only*, an adzyme with "trypsin" as catalytic domain, and "anti-TNFα scFV antibody" as targeting domain.

First of all, Applicants traverse this species restriction requirement on the basis that Applicants are claiming a *genus* of adzyme, rather than a *species* adzyme, or the constituent elements of an adzyme (such as the catalytic domain or the targeting domain, as the Restriction Requirement suggests). The independent *genus* claims (*e.g.*, Claims 1-6) do not recite any specific adzyme *species*. Thus it is inappropriate for the Examiner to restrict the claimed invention to an un-recited *species* in a *genus* claim, because doing so amounts to using Restriction Requirement to limit the scope of independent claims that have not yet been examined on merits. Applicants note that the statutory basis for restriction practice arises under 35 U.S.C. § 121, which authorizes the patent office to require that each patent application be limited to a single invention. However, there is no basis in the statute or the rules (37 C.F.R. §§ 1.141 and 1.142) for the patent office to eliminate inventions from consideration entirely. A genus invention is as much an invention as each species. Thus, when the examiner enumerates the various inventions that Applicants are requested to choose between, examiner is not authorized to omit the generic inventions.

Secondly, Applicants submit that there is no undue search burden on the Examiner to perform a search to cover the scope of the independent claims. Although there can be many choices for the catalytic domain and the targeting domain, all adzymes share the same generic structure. Therefore, a search using generic claim terms (such as "protease domain," and/or "fusion protein," etc.) would necessarily encompass a broad search that can adequately cover the claimed subject matter. Pursuant to MPEP 803, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Thus no serious search burden will result if the Restriction Requirement is withdrawn.

Lastly, Applicants believe that requiring Applicants to elect a specific species adzyme so that sequence searches may be performed is not a sound or effective alternative to the suggested search above. For example, catalytic domains such as "trypsin" came into the art long before its

actual sequence is known. Thus searching sequence database may not even reveal the best available art for the claimed invention.

Accordingly, reconsideration and withdrawal of the Restriction Requirement is respectfully requested.

Presently, Claims 1, 2, 4-35, 37, 38, 40-44, 52, 53, 56, 58, 60, 66, 68-82, 84-86, 90-102, 104, 107, 108, 110, 113-120, and 127-134 read on the elected species.

In addition, Applicants note that all claims are generic claims linking elected and non-elected species. Pursuant to MPEP 809.04, "[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim." Thus, restrictions imposed on species encompassed by generic claims must be withdrawn upon indication of an allowable generic claim (MPEP 809). In other words, upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141 (MPEP 809.02(a)).

Furthermore, the burden is on the Examiner to examine these generic claims throughout their scope, together with any claims dependent thereon drawn to non-elected species or inventions, rather than for Applicants to limit the scope of the generic claims to conform to the scope of any species or inventions listed in a Restriction Requirement.